K082865
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OCT 23 2008

# 510(k) Summary

**Submitter of the Application**

Name: Gorbec Pharmaceutical Services Inc.

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Contact Person: Sandra R. Kircus
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**Trade Name**

Zenieva

**Common name**

Hydrogel wound dressing

**Device Classification**

21 CFR 878.4022 "Dressing, Wound, Hydrogel"
Class I Non-Exempt, NAE.

**Substantial Equivalence / Predicate Device**

Gorbec Pharmaceutical Services Inc. believes the modification submitted for Zenieva is substantially equivalent to the currently approved device, cleared under K073246.

**Device Description and Design**

Zenieva is a non-sterile, semi-viscous emulsion intended for topical application. It is presented for prescription (requires a physician diagnosis of disease state) use. The product is formulated as an oil-in-water emulsion containing a cross-linked polyacrylic acid polymer, natural gum, and cellulose as thickening agents. The oil composition of Zenieva is composed of glyceride, squalane, lecithin, and fatty acids.

**Intended Use of the Device**

Zenieva is used to manage and relieve the burning and itching experienced with various types of dermatoses, including radiation dermatitis, atopic dermatitis, and allergic contact dermatitis. Zenieva helps relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

This intended use is the same intended use as previously cleared for Zenieva; therefore there is no issue with determining differences in the safety and efficacy as related to the predicate device as related to intended use.

**Technological Comparison to Device Predicate Device**

The proposed modification to Zenieva does not change the chemical composition, intended indications for use, physical properties, or claims. Research has shown that a labeling change – adding a contraindication for one of the ingredients – is necessary. This is adding safety to the product.

**Non-Clinical Performance Data**

N/A

**Conclusion**

The product's ingredients and performance characteristics have remained unchanged. Tests and performance data are not applicable; research has shown that adding a contraindication statement for an ingredient is necessary. The product itself is not being modified; we are putting the appropriate measures in place to increase the product's safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2008

Gorbec Pharmaceutical Services, Inc.
% Sandra R. Kircus, Ph.D.
Regulatory Affairs Manager
2445 South Alston Avenue
Durham, North Carolina 27713

Re: K082865
Trade/Device Name: Zenieva
Regulation Number: 21 CFR 878.4022
Regulation Name: Hydrogel wound dressing and burn dressing
Regulatory Class: I
Product Code: NAE
Dated: September 26, 2008
Received: September 30, 2008

Dear Dr. Kircus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known):
Device Name: Zenieva

Zenieva is used to manage and relieve the burning and itching experienced with various types of dermatoses, including radiation dermatitis, atopic dermatitis, and allergic contact dermatitis. Zenieva helps relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

| Prescription Use X | AND/OR | Over-The-Counter Use |
|---|---|---|
| (Part 21 CFR 801 subpart D) | | (21 CFR 801 Subpart C) |

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Neil R Ogden for mkm

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K082865